

10/591100

Substitute Specification (Marked-up Version)

IAP9 Rec'd PCT/PTO 30 AUG 2006

**Catheter for aspirating, fragmenting and removing removable material from blood vessels**

**CROSS-REFERENCES TO RELATED APPLICATIONS**

[0001] The present invention claims priority to International Application No. PCT/IB2005/000543, designating the United States of America, filed March 3, 2005, and published September 15, 2005, under International Publication No. WO 2005/084562 A2, which claims priority to Swiss Patent Applications 0369/04, filed March 3, 2004, and 2176/04, filed December 22, 2004.

**BACKGROUND**

**Field of the Invention**

[0002] The invention relates to a catheter for aspirating, fragmenting and removing removable materials from hollow bodies, in particular thrombi and emboli from blood vessels, comprising a working head which is axially displaceable over a guide wire independently thereof and is arranged at the distal end of the catheter and which has at least one lateral opening, the catheter having a flexible transport screw which can be caused to rotate by means of a rotary drive of a drive unit remote from the working head, and comprising a flexible tube surrounding the transport screw, connected to the working head and intended for removing the detached thrombi and emboli fragments and a cutting tool.

**Description of Related Art**

[0003] Such catheters are used in particular for the treatment of occlusive arterial diseases by aspiration, fragmentation and removal of emboli and thrombi. They are introduced into the

artery or vein and advanced, preferably with X-ray monitoring, up to the narrowed or blocked area whichthat is to be treated. A fragmentation tool drivable in a rotary manner by means of a rotary drive, and a working head, are arranged at their front or distal end.

**[0004]** In the case of these catheters, a distinction should be made as a rule on the basis of two different fields of use:

A) Atherectomy

This is the removal of, as a rule, hard deposits whichthat have adhered to the vessel walls over many years.

B) Thrombectomy

This is the removal of fresh blood clots whichthat accumulate at bottlenecks and lead to blockage of the blood vessels (emboli).

**[0005]** A rotational catheter disclosed, for example, in European Patent No. EP 0 267 539 B1 and intended for atherectomy has, as a cutting tool, a substantially ellipsoidal cutter whose surface is provided with abrasive material and whichthat is driven via a flexible drive shaft by a rotary drive arranged at the proximal end of the catheter at a speed of up to 160,-000 rpm. The cutter is connected to the flexible drive shaft. The drive shaft runs in a tubular sheath serving as a catheter tube. A guide wire, which is introduced into a blood vessel before the introduction of the catheter, and is advanced to the area to be treated or slightly beyond, and serves as a guide for the cutter and the drive shaft, extends through the drive shaft.

**[0006]** In the case of these known rotational catheters, the risk that the vessel wall will be injured and in certain circumstances even perforated, particularly in pronounced curves of the blood vessel, cannot be ruled out.

**[0007]** A further rotational catheter disclosed in US Patent No. 5,-571,-122 ~~A~~ has a cutting tool with a multiplicity of peeling knives extending in the axial direction and driven at a speed of about 800 rpm. By axial compression of the cutting tool, the peeling knives can be caused to bulge radially outward and the external diameter of the cutting tool is thus increased. In the case of this catheter, there is the risk that, particularly as a result of the relatively slow circumferential speed, the peeling knives may pull, drag or jam against the vessel wall, with the result that the blood vessels react dramatically in that they contract and thus prevent further intervention.

**[0008]** US Patent No. 5,-226,-909 discloses another atherectomy catheter ~~whichthat~~ has, on its working head, a sleeve-like or helical cutting element drivable by a rotary drive and/or displaceable in the axial direction. The opening of the working head is pressed against the deposits adhering to the vessel wall by means of a lateral inflatable balloon. These deposits are then comminuted by rotation or axial advance of the cutting element and are collected in a chamber. The chamber must then be emptied from time to time by withdrawing the catheter. Continuous removal of comminuted deposited material is not envisaged.

**[0009]** PCT Patent Publication No. WO 96/29941 A1 describes a rotational catheter for atherectomy, whose working head ~~consists of~~includes a stationary stator, connected to a tube, and a rotor. The rotor is rotatable relative to the stator by means of a high-speed transport/drive screw. Both the stator and the rotor have, at their circumference, windows ~~whichthat~~ can be caused to coincide. As a result of shearing between a cutting edge on the rotor and an opposite cutting edge on the openings

of the stator, comminution of the parts projecting into or sucked into the openings is effected. The rotor may surround the stator on the outside ("outer rotor") or may be arranged in the interior of the stator ("inner rotor").

[0010] Catheters having inner and outer rotors with cutting edges ~~which~~that operate around the catheter axis have the disadvantage that they stir up blood and occlusion material, so that the blood flow from proximal to distal may wash away particles ~~which~~that may again produce blockages and blood flow problems in other areas of the blood circulation, particularly in small blood vessels.

[0011] Further documents relating to the prior art include EP and PCT Publications, EP Patents, and US Patents having the following numbers are: EP 0 310 285 A2; EP 0 448 859 A2<sub>7i</sub>; EP 0 669 106 A2<sub>7i</sub>; EP 0 680 730 A2<sub>7i</sub>; EP 0 669 106 B1<sub>7i</sub>; EP 0 739 603 A1<sub>7i</sub>; WO 02/49690 A2<sub>7i</sub>; US 4,-857,046 and US 5,100,426.

[0012] Rotational catheters known to date and comprising revolving knife-like elements or cutters require a relatively powerful rotary drive, which in turn necessitates a more powerful, rotationally--more--rigid catheter tube for compensating the moment of reaction ~~which~~that arises during cutting of particles, in order that the catheter tube does not rotate about the longitudinal axis. However, a stronger or rotationally--more--rigid tube is inevitably less flexible, with the result that the catheter is in certain circumstances disadvantageous in the curves of blood vessels.

[0013] It is the object of the invention to provide a catheter ~~of the type mentioned at the outset~~, in particular for thrombectomy, ~~which~~that has no externally revolving cutting

knife, cutter or the like, operates in an atraumatic manner and can aspirate and fragment thrombi and emboli in the blood vessel and transport them through the catheter tube continuously out of the vessel.

[0014] It is therefore intended to achieve a reduction in components and to minimise the risk of injury to walls of blood vessels. The advantages of known systems, in particular those of the system according to PCT Publication No. WO 96/29941 A1 are however to be retained.

#### SUMMARY OF THE INVENTION

[0015] In accordance with one or more embodiments of the present invention, a catheter for aspirating, fragmenting and removing removable materials from hollow bodies, in particular thrombi and emboli from blood vessels, comprises a working head that is axially displaceable over a guide wire independently thereof, is arranged at the distal end of the catheter, and has at least one lateral opening. The catheter also may include: a flexible transport screw, operable to rotate by means of a rotary drive of a drive unit remote from the working head; and a flexible tube, which surrounds the transport screw, connects to the working head, and facilitates removal of the detached thrombi and emboli fragments; and a cutting tool.

[0016] According to the invention, the object of the invention is achieved if the transport screw in the region of the working head is in the form of a shearing cutting tool cooperating with the opening of the working head in order to continuously to comminute the penetrating materials or aspirated and/or detached thrombi and emboli between the peripheral borders of the transport screw and borders of the openings. The transport

effect of the transport screw is retained as in the design according to PCT Publication No. WO 96/29941 A1.

**[0017]** The transport screw thus performs an additional function, namely the comminution of the deposit particles and tissue particles aspirated in the transport direction into the openings by the action of the reduced pressure. In contrast to the prior art, this comminution takes place not rhythmically when cutting edges come into contact with one another but continuously. The internally rotating and internally cutting transport screw in the working head aspirates and comminutes the deposits without causing vortices outside. The risk that particles will be washed away and that there will be blood flow disturbances distally due to catheter intervention is therefore absent.

**[0018]** There are also virtually no vibrations, which in principle ~~it is wished~~ are desirable to avoid in the case of blood vessels. Since a lower reaction torque is necessary as a result of the continuous cutting, the tube may also have a thinner wall and be more elastic. This is also the case in particular because the cutting force generated during fragmentation acts mainly in the axial direction (proximally) and not, as in the prior art described, in the circumferential direction. The torsional load of the tube is therefore very small.

**[0019]** The working head is preferably, ~~and as known per se shown~~, cylindrical, having one or more window-like openings, such as bores or shaped slots, ~~being~~ arranged at the circumference. As a result of the cooperation of the high speed rotating transport screw ~~rotating at high speed~~ and the inner wall of the cylindrical working head, or ~~with~~ the edges of the

~~openings, the result is a rotary cutting tool which is provided that has good fragmentation power with a relatively low torque or low drive power.~~

**[0020]** Compared with the prior art disclosed in PCT Publication No. WO 96/29941 A1, at least one of the components of the working head, namely the rotor, is omitted. This leads to a simplification and cost reduction. Furthermore, because of the lack of a rotor, jamming between rotor and stator cannot occur. In addition the design according to the invention permits the reduction of the external diameter to small dimensions not realizable to date. Such small dimensions are required, for example, for the treatment of coronary vessels.

**[0021]** The transport screw is expediently formed, in the region of the working head, as a shearing cutting tool ~~which that~~ cooperates with the opening of the working head and, in the operating state, continuously comminutes the penetrating materials or aspirated and/or detached thrombi and emboli between the peripheral borders of the transport screw and borders of the openings,~~—and removinges~~ said materials or thrombi or emboli along the transport surface in the direction of the proximal end.

**[0022]** The transport screw is, in the region of the working head, advantageously in the form of a shearing cutting tool ~~which that~~ cooperates with the opening of the working head and, in the operating state, continuously comminutes the penetrating material or aspirated and/or detached thrombi and emboli between the peripheral borders of the transport screw and borders of the openings,~~—and removinges~~ said materials or thrombi or emboli along the transport surface.~~—, and —t~~ The lateral opening of the working head is in the form of an L-shaped slot having a limb

extending substantially in the longitudinal direction and a limb extending along a part of the circumference. The thrombi and emboli to be removed can therefore be drawn in or sucked along the limb extending in the longitudinal direction into the interior of the working head and then sheared off by means of the transport screw at the proximal edge of the limb extending in the circumferential direction.

**[0023]** The ratio of the width of the limb, extending in the longitudinal direction, to the width of the limb, extending in the circumferential direction, is from 1.0 to 1.3. Thus, good transport of the aspirated thrombi and emboli in the direction of the proximal end and subsequent clean shearing off are permitted.

**[0024]** The distal part of the transport screw, in the region of the working head, is formed in the external diameter to be an exact fit with the internal diameter of the preferably cylindrical working head, so that the external diameter of the transport screw results in only minimal diameter play relative to the inner lateral surface of the working head. This prevents fragmented elements from being able to become jammed between the transport screw and the internal diameter of the working head.

**[0025]** The edges on the outside of the transport screw are advantageously formed so as to be sharp in the region of the opening of the working head. This permits a good and clean shearing off of generally very tough thrombi and emboli to be removed.

**[0026]** The working head is expediently tapered toward its distal end. This ensures that the catheter can also be advanced by sliding in narrow radii of curvature of the vessels without

great resistance. Thus, it cannot become hitched to the vessel wall or to projections.

**[0027]** The edges of the lateral openings are advantageously formed to be sharp at least in regions on the inside. This together with the periphery of the transport screw permits a clean shearing process for fragmenting the thrombi or emboli. The openings of the catheter head are designed so that the transport screw rotating at high speed fragments thrombi and emboli ~~whichthat~~ are aspirated at the inner sharp edges of the openings and the outer diameter of the transport screw to form pieces. These pieces are transported in the direction of the rotary drive by the prevailing suction and the screw transport.

**[0028]** The edges of the lateral opening are rounded, expediently at least in regions, on the lateral surface of the working head. This permits vortex-free flow of the deposits to be removed and of other body fluids in the region of the working head.

**[0029]** The lateral opening in the working head is advantageously in the form of a slot. Slots can be easily produced and can be adapted to requirements in their dimensions.

**[0030]** It is expedient if the slot runs at least partly in the axial direction of the working head. By changing length and width, the slot can be adapted according to the different requirements of the different applications.

**[0031]** An advantageous embodiment ~~consists in~~ includes the slot being formed, relative to the longitudinal axis of the working head, at least partly along a helix. Optimum adaptation to the respective circumstances is also possible by means of the helix angle or the direction of rotation of the helix. The direction

of rotation of the helix can be identical to or different from the direction of rotation of the transport screw. An identical direction of rotation gives a drawn out cut over a larger cutting length. This is advantageous in particular for tough or fibrous material to be removed. An opposite direction of rotation gives a short cut and tends to be suitable for brittle material.

**[0032]** For certain applications, it is expedient if the width of the slot decreases toward the proximal end of the working head. The deposits sucked in to the slot, such as thrombi or emboli, are thus forced toward the proximal end against a bottle neck, which permits improved fragmentation of the deposits.

**[0033]** An advantageous embodiment ~~consists-in~~includes forming the slot as an L-shape. The slot may ~~consist~~include, for example, of a part running in the axial direction and a part connected to this and running in the circumferential direction.

**[0034]** Expediently, at least one groove-like recess starting from the distal end and opening into the lateral opening is formed in the distal end region of the working head. This groove-like recess forms a channel through which thrombi, emboli and/or other deposits can therefore also be aspirated from the distal end, can reach the region of the lateral opening and can be comminuted by the cooperation of the transport screw with the working head.

**[0035]** It is advantageous if the depth of the groove-like recess increases toward the proximal end of the working head. This can be achieved on the one hand if the working head tapers toward the distal end or if the base surface of the recess is arranged so as to be inclined relative to the longitudinal axis

of the working head. As a result of the increasing depth, the flow cross-section is increased toward the proximal end and hence the deposits are more easily transported away.

**[0036]** The width of the groove-like recess is expediently greater than the chord of the internal diameter of the working head in the region of the groove base. This gives rise to clean edges, along which the deposits are sucked into the interior of the working head in order to be subsequently fragmented there.

**[0037]** The working head is advantageously connected to the tube axially so as to be resistant to tension and pressure. Since in practice only a small reaction torque is exerted on the tube, in contrast to the prior art, the requirements with regard to the connection between the working head and the tube and with regard to the torsional rigidity of the tube itself are relatively low so that, for example, a simple press-fit or adhesive connection is possible and the tube may be very elastic.

**[0038]** As a result of the flow caused by the transport screw, reduced pressure results in the tube. In order to increase the flexibility of the tube, it is expedient if the tube has a reinforcement at least in sections. As a result of the reinforcement, the wall thickness of the tube can also be kept thinner and the flexibility can thus also be increased. A reinforcement also has a stabilizing effect on the play between the inner wall of the tube and the external diameter of the transport screw.

**[0039]** The reinforcement is advantageously in the form of a metallic helix. Such a helix has a high flexibility in the bending direction and good tensile and compressive strength.

**[0040]** For production and also for use during insertion of the catheter, it is expedient to arrange the reinforcement on the inside of the tube. This permits a smooth surface on the outside of the catheter. However, the reinforcement can also be embedded completely in plastic.

**[0041]** An advantageous embodiment ~~consists in~~ includes forming the tube in two parts, the proximal part being in the form of a pure plastic tube and the distal part facing the working head being in the form of a metallic helical spring having a thin-walled elastic plastic sheath. Thus, the distal part of the tube is particularly flexible and the catheter can be advanced and withdrawn virtually without effort even around narrow curves.

**[0042]** The working head and/or the transport screw expediently ~~consist comprise of~~ metal. In particular, stainless steels or other corrosion-resistant alloys are suitable.

**[0043]** With regard to improved material properties, the working head can alternatively also be composed of sintered ceramic or metal ceramic or have a highly resistant layer for protection from wear.

**[0044]** Further developments of the invention and variants thereof are indicated in the dependent patent claims and in the figures and the description of the drawings.

**[0045]** It is true that in the above text reference is made to a catheter for aspiration, fragmentation and removal, in particular from human blood vessels; however, the invention is not limited thereto but rather is also available to other users for analogous applications in the medical sector (e.g. reopening occluded organ regions, such as, for example, ureter, bile duct

or fallopian tube and vascular prostheses and so-called stents). The patent claims should accordingly be interpreted broadly.

**[0046]** The list of reference numerals and the drawing together with the subject matter described or protected in the claims, form integral parts of the disclosure of this Application.

**[0047] DESCRIPTION OF FIGURES**

**[0048]** The figures are described in relation to one another and overall. Identical reference numerals denote identical components, and reference numerals with different indices indicate functionally identical components.

**[0049]** The figures show the following by way of example:

**[0050]** Fig. 1 shows the schematic overall setup of a device having a catheter according to the invention;

**[0051]** Fig. 2 shows a view of the working head of a catheter according to fig. 1;

**[0052]** Fig. 3 shows the working head according to fig. 2, in longitudinal section;

**[0053]** Figs. 4 and 5÷ show a variant of the working head in perspective view;

**[0054]** Figs. 6 to 10÷ show a variant of the working head with a rectangular lateral opening;

**[0055]** Figs. 11 to 15÷ show a variant of the working head according to figs. 6 to 10, with a narrow slot extending in the longitudinal direction;

- [0056] Figs. 16 to 20÷ show a variant of the working head with an approximately square lateral opening;
- [0057] Figs. 21 to 25÷ show a variant of the working head with a slot-like opening extending in the circumferential direction;
- [0058] Figs. 26 to 30÷ show a variant of the working head with a groove-like recess starting from the distal end and opening into the lateral opening;
- [0059] Figs. 31 to 35÷ show a variant of the working head with a lateral opening in the form of a longitudinal slot and a groove-like recess starting from the distal end and opening into the lateral opening;
- [0060] Figs. 36 to 40÷ show a variant of the working head with an approximately triangular lateral opening whose width tapers toward the proximal end;
- [0061] Figs. 41 to 45÷ show a variant of the working head with a lateral opening which consists of comprising a region extending in the axial direction and a region extending over a part of the circumference;
- [0062] Figs. 46 to 50÷ show a variant of the working head analogously according to figs. 41 to 45, the region extending over a part of the circumference running in the opposite direction;
- [0063] Figs. 51 to 55÷ show a variant of the working head analogously according to figs. 41 to 45, the region extending in the longitudinal direction being substantially longer;
- [0064] Figs. 56 to 60÷ show a variant of the working head analogously according to figs. 51 to 55, the region extending

over a part of the circumference running in the opposite direction according to the setup according to figs. 51 to 55;

[0065] Figs. 61 to 65÷ show a variant of the working head with a lateral opening extending along a helix;

[0066] Figs. 66 to 70÷ show a variant of the working head analogously according to figs. 61 to 65, that with the region of the opening, which runs along a helix, opening at the distal end emptying into a region running in the axial direction;

[0067] Figs. 71 to 75÷ show a variant of the working head analogously according to figs. 66 to 70, that with the region of the opening, which runs along a helix, being oriented in the opposite direction of rotation; and

[0068] Figs. 76 to 80÷ show a variant of the working head analogously according to figs. 66 to 70, with a groove-like recess starting from the distal end and opening into the lateral opening running along a helix.

#### DETAILED DESCRIPTION

[0069] Fig. 1 schematically shows the overall setup of a medical device for use of the catheter according to the invention. The device has a drive unit 1 with a rotary drive 2. An injection chamber 3 is present at the front end of the rotary drive. This is connected via a removal channel 4 to a collecting container 5. A guide wire 6 passing through the drive unit has a proximal (rear) end 7 and a distal (front) end 8. A movable insertion lock 9 is located upstream of the injection chamber 3. This setup corresponds substantially to that of PCT Publication No. WO 96/29941 A1. Design details can

also be taken over from that reference, which comprises part of the knowledge of a person of ordinary skill in the art.

[0070] A catheter designated as a whole by 10 substantially comprises a flexible tube 12 and a working head 11 connected thereto in a manner resistant to tension and pressure. The guide wire 6 passes through the catheter 10, the distal end 8 projecting beyond the working head 11.

[0071] The working head 11a visible in figs. 2 and 3 and shown on a larger scale and partially in section has a lateral opening 14a. A helical transport screw 13 surrounds the guide wire 6 and is matched in external diameter exactly to the internal diameter of the working head 11a. The opening 14a has an inner edge 15 which ~~that~~ is sharp and an outer border 16 which ~~that~~ is rounded. At the edge 15, the deposits which ~~that~~ are sucked by the reduced pressure generated by the transport screw 13 into the interior of the working head 11a are fragmented by shearing off by the periphery of the transport screw 13, which cooperates with the edge 15, and are transported by means of the transport screw 13 in the direction of the drive unit 1 through the tube 12.

[0072] The section shown in fig. 3 shows the setup of the tube 12. This preferably consists of ~~comprises~~ a reinforcement 17 wound, for example, from a fine wire and a thin plastic sheath 18. This setup gives very high flexibility of the tube 12, which is advantageous particularly in the distal region of the catheter 10. For production and cost reasons, the proximal region of the tube can also be in the form of a customary thicker plastic tube, it being possible for the two regions to be connected to one another, for example, by shrinkage or adhesive bonding. One variant comprises the joint covering of

the reinforcing tube and of the connecting proximal part of the tube with a thin, closely fitting covering.

[0073] The working head 11b shown in figs. 4 and 5 has an opening 14b ~~which~~that substantially comprises a longitudinal slot 20 and a circumferential slot 21 extending along a part of the circumference. A groove-like recess 19a starting from the distal end opens into the longitudinal slot 20. This formation makes it possible to handle the deposits in front of the working head 11b. The working head 11b tapers toward the distal end. This facilitates the advance of the catheter in the duct or blood vessel to be freed from obstruction.

[0074] Figs. 6 to 80 show different variants of the formation of the lateral opening in the working head. However, these diagrams are not limiting but are to be understood merely by way of example. Further embodiments and also combinations of the formations shown are conceivable.

### List of reference numerals

- |  |                        |
|--|------------------------|
| 1  | Drive unit             |
| 2  | Rotary drive           |
| 3  | Injection chamber      |
| 4  | Removal channel        |
| 5  | Collecting container   |
| 6  | Guide wire             |
| 7  | Proximal end           |
| 8  | Distal end             |
| 9  | Insertion lock         |
| 10   | Catheter               |
| 11a, 11b, 11c, 11d, 11e, 11f, 11g, 11h, 11i, 11k, 11l, 11m, 11n, 11o, 11p, 11q | Working head           |
| 12   | Tube                   |
| 13   | Transport screw        |
| 14a, 14b, 14c, 14d, 14e, 14f, 14g, 14h, 14i, 14k, 14l, 14m, 14n, 14o, 14p, 14q | <u>Lateral Opening</u> |
| 15   | Edge                   |
| 16   | Border                 |
| 17   | Reinforcement          |
| 18   | Sheath                 |
| 19a, 19b, 19c  | Groove-like recess     |
| 20   | Longitudinal slot      |
| 21   | Circumferential slot   |

## **ABSTRACT**

Catheter for the aspiration, fragmentation and removal of removable material from hollow bodies, in particular of thrombi and emboli from human blood vessels, comprising a working head, a flexible transport screw, a flexible tube, and a cutting tool. The working head (11) which is independently displaceable along a guide wire (6) independently thereof, and is arranged at the distal end of the catheter, and which has at least one lateral opening (14), the catheter (10) having a The flexible transport screw (13) which can be rotated at a distance by means of a rotary drive (2) of a drive unit (1), which rotary drive is a distance away from the working head (11), and comprising a The flexible tube (12) surrounding the transport screw (13), is connected to the working head (11) and is intended for removing the detached thrombi and emboli fragments, and a cutting tool, the transport screw (13) being in the forms of a shearing cutting tool in cooperation with the lateral opening (14) of the working head (11), in order to comminute the detached thrombi and emboli between the peripheral borders (13a) of the transport screw (13) and borders of the lateral openings (14).

(Fig. 3)